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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,600	02/03/2004	Oleg Fedorkin	2002645-0021	2207
24280	7590	09/11/2006	EXAMINER	
CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/770,600	Applicant(s) FEDORKIN ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-69 and 82-106 is/are pending in the application.
- 4a) Of the above claim(s) 53,54,57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-52,55,56,59-69 and 82-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election of the species in which the first virus is a tobamovirus, the second virus is an alfamovirus and the component is a replicase coding component in the reply filed on 23 June 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 53, 54, 57 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 June 2006. The withdrawn claims do not encompass the elected species.

The disclosure is objected to because of the following informalities:

Pages 31 and 33-35 of the specification disclose nucleic acid sequences, but do not disclose therewith embedded sequence identifiers (e.g., "SEQ ID NO:") as required by 37 CFR § 1.821(d).

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

The drawings are objected to because Figures 2 and 4 are merely text lists of viral genes or components, and should be moved into the specification as tables and deleted as figures. The remaining figures must be amended so that their numbering is continuous. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50-52, 55, 56, 59-69, 84 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Spitsin et al. (U, newly cited).

In claim 50, the elected species is drawn to a vector comprising one or more replicase protein coding components from a tobamovirus, and a partial or complete 3' untranslated region from an alfamovirus. Claim 51 recites that the 3' untranslated region facilitates systemic spread of the virus, whereas claim 52 recites that it comprises a recognition site for complexing a coat protein. Claim 55 is limited to alfamovirus as the second virus. Claim 56 specifies that this is alfalfa mosaic virus. Claim 59 recites that the 3' region comprises at least a portion of alfamovirus RNA3 gene, more narrowly specified as alfalfa mosaic virus in claim 60. Claims 61 and 62 specify that the recited segments of alfalfa mosaic virus RNA3 gene are present. Claim 63 specifies that the first virus is a tobamovirus, and claim 64 further specifies that it is tobacco mosaic virus. Claim 65 specifies that the viruses are tobacco mosaic virus and alfalfa mosaic virus. Claim 66 specifies the presence of at least part of the 3' untranslated region of the first virus. Claim 67 specifies which part of said untranslated region is present. Claims 68 specify DNA and RNA vectors, respectively. Claim 84 specifies that the vector encodes a replicase protein, as does claim 85.

Spitsin et al. teaches, e.g., at the Abstract and Figure 1, a vector in which the full length cDNA of the RNA4 gene (and therefore a portion of the RNA3 gene) has been substituted into a tobacco mosaic virus vector (which was rendered defective for coat protein production by

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removal of the initiation codon in the resident coat protein gene but not by disabling the replicase). This construct necessarily has the entire 3' untranslated region of the RNA4 gene, as it is the cDNA. The 3' untranslated region must inherently facilitate systemic infection and coat protein recognition, in that the recombinant virus of Spitsin et al. functioned accordingly. The vector is also disclosed in RNA form at page 2553, left-hand column, first full paragraph, wherein it is taught that transcripts were used to inoculate plants. Also, when the DNA form of the vector replicates, it would inherently do so through the RNA form.

Claims 50, 55, 56, 66, 68 and 86 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhu et al. (A, newly cited).

In claim 50, embodiments outside of the elected species include those drawn to a vector comprising one or more components from a plant virus, and a partial or complete 3' untranslated region from another plant virus. Claim 55 is limited to alfamovirus as the second virus. Claim 56 specifies that this is alfalfa mosaic virus. Claim 66 specifies the presence of at least part of the 3' untranslated region of the first virus. Claim 68 specifies that the vector is a DNA vector. Claim 86 specifies that the vector further encodes a polynucleotide of interest.

Zhu et al. teaches, e.g., at Figures 11A and 11B, and the description thereof at column 8, second full paragraph, a viral vector comprising portions of several plant viruses, specifically CaMV 35S enhancer and promoter, the gene segment encoding the alfalfa mosaic virus RNA4 leader sequence, Grapevine leafroll virus (type 2) coat protein gene (which is the gene of interest), and CaMV 35S 3' untranslated region.

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The instant rejection shows that the above embodiments outside of the elected species were discovered in the search for the elected species. However, as stated above, the species election set forth in the response filed 23 June 2006 stands.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-52, 55, 56, 59-69 and 82-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention is drawn to a viral vector which is a chimera of two other viruses. However, it is apparent that the components of a virus must interact for there to be function, e.g., infectivity. Bendahmane et al. (V, newly cited) teaches, e.g., in the Abstract, that the mere presence or absence of a mutation in tobacco mosaic virus coat protein can increase or decrease of the movement protein, which directly affects virus spread. Sit et al. (W, newly cited) teaches, e.g., as summarized in the abstract, that mere assembly of dianthoviruses is not sufficient for systemic movement. Thus, it is apparent that the mere presence of expressed components of a virus together is not sufficient to predict function, given any sort of change or mutation.

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Therefore, in the more radical case of substituting one component for another, even where the functions were related, there can be no prediction of the ability of that new component to associate functionally with a second component of the original virus. The relationship of structure to function for proteins and protein interactions is not well characterized as a theory or algorithm in the art, and the specification does not remedy this deficiency in the art. As such, one of skill in the art would not have recognized that Applicants were in possession of the full scope of the claimed invention at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 94, 95 and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 94 and 95 recite “the first and second polypeptides”. However, there is insufficient antecedent basis for this phrase.


Claims 95 and 104 recite the phrase “proteins of pharmaceutical interest.” However, it is not clear what this phrase means. It might be understood to encompass pharmaceutical proteins, proteins which are putative pharmaceuticals, or any protein merely being tested as a putative pharmaceutical. It might have been that “pharmaceutical proteins of interest” was intended.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
29 August 2006



JAMES KETTER
PRIMARY EXAMINER
2006